Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GENENTECH, INC. and HOFFMANN-LA ROCHE INC., **Plaintiffs,** **v.** **SANDOZ, INC. and LEK PHARMACEUTICALS D.D.,** **Defendants.**	**Civil Action No. 23-4085 (ES) (LDW)** **OPINION**

SALAS, DISTRICT JUDGE

Before the Court is Defendants'[1] appeal of the March 5, 2024 Opinion and Order of the Honorable Leda D. Wettre, U.S.M.J., denying Defendants' motion to transfer this matter to the United States District Court, District of Delaware (D.E. No. 56 ("March 5 Opinion" or "Mar. 5 Op.")). (D.E. No. 57 ("Appeal"); *see also* D.E. No. 57-1 ("Mov. Br.")). Plaintiffs opposed (D.E. No. 58 ("Opp. Br.") and Defendants replied (D.E. No. 60 ("Reply Br.")). The Court has considered the parties' submissions and decides this Appeal without oral argument. *See* Fed. R. Civ. P. 78(b); *see also* L. Civ. R. 78.1(b). For the reasons below, the Court **AFFIRMS** the March 5 Opinion and **DENIES** Defendants' Appeal.

I. BACKGROUND AND PROCEDURAL HISTORY

The Court briefly recites the factual background and procedural history necessary for resolution of the instant Appeal. On July 31, 2023, Plaintiffs initiated this action alleging one

[1] Defendants are Sandoz Inc. ("Sandoz") and Lek Pharmaceuticals D.D. ("Lek," together with Sandoz, "Defendants"). Plaintiffs are Genentech, Inc. ("Genentech") and Hoffman-La Roche Inc. ("HLR," together with Genentech, "Plaintiffs").

count of infringement of United States Patent No. 10,188,637 (the "'637 Patent"), entitled "Granulate Formulation of 5-Methyl-1-Phenyl-2-(1H)-Pyridone and Method of Making the Same." (D.E. No. 1 ("Complaint" or "Compl.") ¶¶ 15 & 44–56). The '637 Patent covers a novel tablet formulation of pirfenidone, a drug approved for treatment of idiopathic pulmonary fibrosis ("IPF"). (*Id.* ¶ 1). On January 29, 2019, the United States Patent and Trademark Office issued the '637 Patent, which expires on or about March 28, 2037. (*Id.* ¶ 15). Genentech holds approved New Drug Applications ("NDAs") for pirfenidone capsules and tablets, each 267 mg, as well as 801 mg tablets, all of which are prescribed and sold under the Esbriet® trademark to treat IPF and are covered by the '637 Patent. (*Id.* ¶ 3).

Genentech is a pharmaceutical company incorporated in Delaware and operates its principal place of business in San Francisco, California. (*Id.* ¶ 24). HLR is incorporated in, and operates its principal place of business in, New Jersey. (*Id.* ¶ 26). Sandoz is incorporated in Delaware and operates its principal place of business in New Jersey. (*Id.* ¶ 27). Lek is incorporated in, and operates its principal place of business in, Slovenia. (*Id.* ¶ 28). Lek represents that it is a subsidiary of Sandoz and Novartis. (*Id.* ¶¶ 28–29). As alleged in the Complaint, HLR owns the '637 patent and Genentech is the exclusive licensee. (*Id.* ¶¶ 16, 24 & 26). Plaintiffs assert Genentech "hold[s] all substantial rights to the '637 patent, including the rights to enforce the '637 patent and to seek damages for past, current, and future infringement thereof." (*Id.* ¶ 16).

As alleged in the Complaint, in or around 2019, Defendants and other pharmaceutical companies submitted NDAs seeking approval to market generic Esbriet® tablets and capsules. (*Id.* ¶ 17). Genentech previously sued Defendants as well as other pharmaceutical companies in the District of Delaware, seeking remedies under the Hatch-Waxman Act for alleged patent infringement of twenty allegedly "materially different patents." (*Id.*; *see* D.E. No. 55 (Jan. 12,

2024 Oral Argument Transcript ("OA Tr.")) at 7:10–11 & 22:7–9). The District of Delaware consolidated the prior patent infringement actions in *Genentech, Inc. v. Laurus Labs, Ltd. et al.*, No. 19-0078 (D. Del. Jan. 14, 2019) (the "Pirfenidone ANDA Litigation")). (Compl. ¶ 17). As recognized by Defendants, the '637 Patent "is from a different family [of patents] than the patents that went to trial in Delaware." (OA Tr. at 23:12–14; *id.* at 24:1–4 (admitting that the '637 Patent "bears no family relationship with the patents that were asserted in Delaware")).

The '637 Patent issued during the pendency of the Pirfenidone ANDA Litigation. (Compl. ¶ 18). Plaintiffs maintain the '637 Patent "is unrelated to the patents at issue in the Pirfenidone ANDA Litigation and its claims are materially different and patentably distinct from the claims asserted in that case." (*Id.*). In December 2020, Defendants sent Genentech a Paragraph IV Certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv), in which they maintained that the claims of the '637 Patent were invalid and thus not infringed. (*Id.* ¶ 19).

The other companies involved in the Pirfenidone ANDA Litigation were dismissed on consent between 2019 and 2021. (*Id.* ¶ 20). No generics launched during or immediately after their dismissal. (*Id.*). On March 22, 2022, the Honorable Richard G. Andrews, U.S.D.J., issued a trial opinion as to the remaining defendants, Sandoz and Lek. *Genentech, Inc. v. Sandoz, Inc.*, 592 F. Supp. 3d 355 (D. Del. 2022). In May 2022, after they "prevailed at the district court in the Pirfenidone ANDA Litigation," Defendants launched their generic versions of pirfenidone tablets that allegedly infringe on the '637 Patent. (Compl. ¶¶ 1 & 20). On December 22, 2022, Defendants also prevailed on appeal to the Federal Circuit. *See Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368 (Fed. Cir. 2022). According to Plaintiffs, Defendants launched their generic pirfenidone tablets (267 mg and 801 mg) notwithstanding their knowledge of the '637 Patent's listing in the Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic*

Equivalence Evaluations (the "Orange Book") for Esbriet® tablets. (Compl. ¶¶ 1 & 20). Despite Plaintiffs' request for monetary damages in the "hundreds of millions—if not billions—of dollars in lost profits," they have not sought an injunction to remove any allegedly infringing generic pirfenidone products from store shelves. (*Id.* ¶ 1).

On October 20, 2023, Defendants filed a motion to transfer this action to the District of Delaware based on the Pirfenidone ANDA Litigation, in which Judge Andrews presided. (D.E. No. 47; D.E. No. 47-25 ("Initial Mov. Br.") at 1). On January 12, 2024, Judge Wettre held oral argument on Defendants' motion to transfer. (D.E. Nos. 53 & 55). On March 5, 2024, Judge Wettre denied Defendants' motion to transfer. (Mar. 5 Op.). On March 19, 2024, Defendants appealed the March 5 Opinion to the District Judge. (D.E. No. 57). The Appeal is fully briefed. (Mov. Br.; Opp. Br.; Reply Br.). On September 4, 2024, this matter was reassigned to the Undersigned. (D.E. No. 88).

II. LEGAL STANDARD

A. Appeal of Magistrate Judge Decisions

"Appeals from the orders of magistrate judges are governed by Local Civil Rule 72.1(c)." *McDonough v. Horizon Blue Cross Blue Shield of N.J., Inc.*, No. 09-0571, 2013 WL 322595, at *2 (D.N.J. Jan. 22, 2013). The standard of review of a magistrate judge's decision depends on whether the magistrate judge addressed a dispositive or non-dispositive issue. *Id.* On appeal of a non-dispositive order, such as the March 5 Opinion entered by Judge Wettre in this case, a district court may modify or set aside the magistrate judge's decision if it was clearly erroneous or contrary to law. *Eisai Co., Ltd. v. Teva Pharms. USA, Inc.*, 629 F. Supp. 2d 416, 424 (D.N.J. 2009); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A); *see Siemens Fin. Servs., Inc. v. Open Advantage M.R.I. II L.P.*, No. 07-1229, 2008 WL 564707, at *2 (D.N.J. Feb. 29, 2008) ("A motion to transfer a case

to another district is considered a non-dispositive motion.").

"A Magistrate Judge's finding is clearly erroneous when, although there may be some evidence to support it, the reviewing court, after considering the entirety of the evidence, is left with the definite and firm conviction that a mistake has been committed." *Coyle v. Hornell Brewing Co.*, No. 08-2797, 2009 WL 1652399, at *3 (D.N.J. June 9, 2009) (quoting *Kounelis v. Sherrer*, 529 F. Supp. 2d 503, 518 (D.N.J. 2008)); *Dome Petroleum Ltd. v. Emps. Mut. Liab. Ins. Co.*, 131 F.R.D. 63, 65 (D.N.J. 1990) (quoting *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)). "A [ruling] is contrary to law if the magistrate judge has misinterpreted or misapplied applicable law." *Gunter v. Ridgewood Energy Corp.*, 32 F. Supp. 2d 162, 164 (D.N.J. 1998). "The party filing the notice of appeal bears the burden of demonstrating that the magistrate judge's decision was clearly erroneous or contrary to law." *Marks v. Struble*, 347 F. Supp. 2d 136, 149 (D.N.J. 2004) (quoting *Cardona v. Gen. Motors Corp.*, 942 F. Supp. 968, 971 (D.N.J. 1996)). However, "where a magistrate judge is authorized to exercise [her] discretion, the decision will be reversed only for an abuse of discretion." *Rhett v. N.J. State*, No. 07-1310, 2007 WL 1456199, at *2 (D.N.J. May 14, 2007).

B. Venue Transfer

"A federal district court may transfer a case to another district where it may have been brought, to serve the interests of justice, or for the convenience of the parties and witnesses." 28 U.S.C. § 1404(a); *Lifecell Corp. v. Lifenet Health*, No. 15-6701, 2016 WL 3545752 at *2 (D.N.J. June 28, 2016). The Court must perform a two-part analysis to determine whether a transfer of venue is appropriate. *See Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, No. 22-7528, 2023 WL 1883357, at *2 (D.N.J. Feb. 10, 2023). First, the Court must analyze whether venue would be proper in the transferee district. *See Clark v. Burger King Corp.*, 255 F. Supp. 2d 334, 337 (D.N.J.

2003). Once this step is satisfied, the Court should then "determine whether a transfer would be in the interests of justice." *Id.* (citing *Jumara v. State Farm*, 55 F.3d 873, 879 (3d Cir. 1995)). Such an analysis requires the Court to engage in an "individualized, case-by-case consideration of convenience and fairness regarding which forum is most appropriate to consider the case." *Telebrands Corp. v. Mopnado*, No. 14-7969, 2016 WL 368166, at *10 (D.N.J. Jan. 12, 2016) (internal quotation marks omitted).

The statute itself outlines three factors for a court to consider: (i) the convenience of the parties; (ii) the convenience of the witnesses; and (iii) the interests of justice. 28 U.S.C. § 1404(a). "In addition to the factors set forth in 28 U.S.C. § 1404(a), courts consider a variety of private and public interests when deciding whether a transfer is appropriate in a given case." *Landmark Fin. Corp. v. Fresenius Med. Care Holdings, Inc.*, No. 09-3689, 2010 WL 715454, at *2 (D.N.J. Mar. 1, 2010). The private interest factors include (i) the plaintiff's preferred forum as expressed by the original forum choice; (ii) the defendant's preference; (iii) where the claim arose; (iv) the convenience of the parties; (v) the convenience and availability of witnesses—to the extent that the witnesses may actually be unavailable in one of the fora; and (vi) the location of books and records. *Jumara*, 55 F.3d at 879 (citations omitted).

As for the public interest factors, courts typically consider (i) enforceability of the Court's judgment; (ii) practical considerations that could make the trial easy, expeditious, or inexpensive; (iii) the level of congestion in the respective forums; (iv) the local interest in deciding local controversies at home; (v) the public policies of the forum; and (vi) the familiarity of the trial judge with the applicable state law in diversity cases. *Id.* at 879–80 (citations omitted). This extensive list of factors, however, "is merely a guide, and not all the factors may be relevant or determinative in each case." *LG Elecs., Inc. v. First Int'l. Comput., Inc.*, 138 F. Supp. 2d 574, 587 (D.N.J. 2001).

The analysis is "flexible and must be made on the unique facts of each case." *Ricoh Co., Ltd. v. Honeywell, Inc.*, 817 F. Supp. 473, 479 (D.N.J. 1993).

The burden of establishing the need for a venue change lies with the party seeking the transfer. *Kabushiki Kaisha v. Lotte Int'l Am. Corp.*, No. 15-5477, 2017 WL 4269457, at *2 (D.N.J. Sept. 26, 2017) (citing *Shutte v. Armco Steel Corp.*, 431 F.2d 22 (3d Cir. 1970)). The burden to transfer a case is a heavy one; "unless the balance of convenience of the parties is strongly in favor of defendant, the plaintiff's choice of forum should prevail." *Shutte*, 431 F.2d at 25.

III. DISCUSSION

As a preliminary matter, the parties do not dispute that venue in the District of New Jersey is proper or that this Court can exercise personal jurisdiction over Defendants. (*See generally* Mov. Br.; Opp. Br.; Reply Br.). Nor do the parties dispute that the District of Delaware is an appropriate alternative forum with jurisdiction over the parties. (*See generally* Mov. Br.; Opp. Br.; Reply Br.; *see also* Mar. 5 Op. at 7 ("Genentech does not contest Sandoz's assertion that Delaware would have venue, subject matter jurisdiction, and personal jurisdiction to entertain this action.")). Accordingly, the dispute before Judge Wettre largely centered on the purported relatedness between this matter and the Pirfenidone ANDA Litigation—specifically whether transfer to Judge Andrews in the District of Delaware would promote judicial economy.

Judge Wettre closely analyzed the relevant factors and concluded that "beyond the most superficial level . . . the overlap between [this case and the Pirfenidone ANDA Litigation] is not sufficiently significant to warrant transfer [to the District of Delaware] under 28 U.S.C. § 1404, particularly where the other transfer factors are largely neutral." (Mar. 5 Op. at 4).

A. Judge Wettre's Decision was Not Clearly Erroneous or Contrary to Law

At the outset, Defendants narrow their Appeal to two factors: (i) Plaintiffs' choice of venue

and (ii) "practical considerations—*i.e.*, judicial efficiency arising from Judge Andrews'[s] experience with the prior Delaware litigation." (Mov. Br. at 9). Indeed, Defendants explicitly state that they "do not object to the Magistrate Judge's determination regarding any other factor." (*Id.*). Thus, for purposes of this Appeal, the Court focuses its analysis on the two factors at issue.

For the reasons set forth below, Judge Wettre's discretionary determination to decline transfer was not clearly erroneous or contrary to law. *See, e.g.*, *Siemens Fin. Servs., Inc. v. Patel*, No. 09-5079, 2010 WL 3119520, at *5 (D.N.J. Aug. 5, 2010) ("Magistrate Judge Cecchi had full discretion to rule on the adequacy and appropriateness of the Section 1404(a) transfer motion before her.").

1. Plaintiffs' Choice of Forum

With respect to Plaintiffs' choice of forum, Judge Wettre found Defendants' arguments unpersuasive—namely, Defendants' contention that Plaintiffs' choice of forum should be entitled to little weight because (i) Genentech is not a resident of New Jersey and its New Jersey-based co-plaintiff, HLR, licensed the '637 Patent to Genentech thus leaving HLR with little stake in this matter; and (ii) Genentech is forum shopping to avoid the District of Delaware where it lost the Pirfenidone ANDA Litigation. (Mar. 5 Op. at 8).

First, Judge Wettre concluded that HLR is in its home forum as a New Jersey plaintiff and that its choice of venue remains "entitled to deference" notwithstanding the residency of its co-Plaintiff, Genentech. (*Id.*). Moreover, Judge Wettre dispelled Defendants' portrayal of HLR as a fictious plaintiff based on HLR's exclusive license to Genentech. (*Id.* at 8–9). Specifically, she found Defendants' argument—that "HLR *may have assigned* the patents[2] to Genentech"—

[2] It appears that Defendants' initial moving brief incorrectly referred to the hypothetical assignment of multiple patents (plural) to Genentech. (Initial Mov. Br. at 27). Indeed, paragraph 16 of the Complaint—the source of Defendants' argument—discusses the ownership and exclusive license of the '637 Patent only. (Compl. ¶ 16).

speculative and unsupported by the factual record. (*Id.* (quoting Initial Mov. Br. at 27 (emphasis added))). Judge Wettre also noted Defendants failed to provide information "on the precise terms of the license to support [their] conjecture that HLR relinquished all rights to the ['637] Patent." (*Id.* at 9). Moreover, during oral argument, Judge Wettre noted she would respect Plaintiffs' choice of forum "to the extent it deserves respect" but that this consideration was "not the determinative point" in her view. (OA Tr. at 57:3–16).

Second, Judge Wettre determined Defendants overstated their argument regarding Plaintiffs' purported forum shopping. Specifically, Judge Wettre acknowledged Plaintiffs' non-victorious outcome in the District of Delaware and recognized that they likely would not welcome more litigation before Judge Andrews. (Mar. 5 Op. at 9). However, Judge Wettre also noted Plaintiffs had no obligation to file the instant matter in Delaware following the conclusion of the Pirfenidone ANDA Litigation in 2022. (*Id.*). Thus, Judge Wettre opined Plaintiffs' decision to file this matter in the District of New Jersey cannot be "fairly [ ] portrayed" as "anything more than a permissible strategic decision in high-stakes litigation." (*Id.*). On the other hand, however, Judge Wettre also found that if Plaintiffs purposefully omitted the '637 Patent from the Pirfenidone ANDA Litigation, they did so with Defendants' acquiescence. (*Id.* at 10). Specifically, Judge Wettre commented that Defendants declined to force Plaintiffs' hands in asserting the '637 Patent in the Pirfenidone ANDA Litigation and that Defendants oddly waited nearly two years after the '637 Patent's listing in the Orange Book to file a Paragraph IV certification—leaving Plaintiffs with little incentive to add the '637 Patent to the Pirfenidone ANDA Litigation, which had been past fact discovery and "well on its way toward trial." (*Id.*). Nor did Defendants file a separate declaratory judgment action on the '637 Patent, which it could have done in the District of Delaware. (*Id.*). Accordingly, Judge Wettre found the omission of the '637 Patent from the

Pirfenidone ANDA Litigation in Delaware did not amount to "the type of ***unilateral*** forum manipulation that might diminish the deference due to [P]laintiffs' choice of forum." (*Id.* (emphasis added)). Thus, Judge Wettre concluded the "'paramount' factor of the [P]laintiffs' choice of forum weigh[ed] against transfer." (*Id.*).

On Appeal, Defendants claim the March 5 Opinion failed to consider that HLR transferred all substantial rights in the '637 Patent to Genentech and, as a result, HLR does not have Article III standing to bring this patent infringement suit. (Mov. Br. at 3 & 16–17). Similarly, Defendants argue the March 5 Opinion "failed to properly consider" that Genentech, the '637 Patent's exclusive licensee, is not at home in New Jersey, which should minimize the weight accorded to Genentech's chosen forum. (*Id.* at 16). Defendants claim this failure was "contrary to law." (*Id.*).[3]

i. HLR's Standing

Although Defendants pointedly argue on Appeal that HLR lacks Article III standing to sue on the '637 Patent and is thus an improper party to this case (Mov. Br. at 16–17), they did not squarely raise the issue of standing before Judge Wettre. Rather, a footnote in Defendants' Initial Moving Brief served to preserve their right to raise potential issues regarding Plaintiffs' Article III standing in the future following discovery. (Initial Mov. Br. at 15 n.9 ("To be clear, Defendants do not waive or forfeit any argument that Genentech or HLR lack Article III standing ***should***

[3] In addition, Defendants generally contend the March 5 Opinion overstated the weight applicable to Plaintiffs' choice of venue. (Mov. Br. at 3 & 16). However, Defendants' assertion that "Plaintiffs' choice of venue (New Jersey), . . . was accorded ***'paramount' weight*** against transfer" (*id.* at 9 (emphasis added); *see also id.* at 16) misconstrues the March 5 Opinion, which only emphasized the paramountcy of the factor, rather than the amount of weight given to it. (*See* Mar. 5 Op. at 10 (concluding that "this ***'paramount' factor*** of the [P]laintiffs' choice of forum weighs against transfer" (emphasis added))). As Plaintiffs argued (*see* Opp. Br. at 23–24), Judge Wettre acknowledged that in Third Circuit, a plaintiff's choice to litigate in its home forum (as HLR did here) is a "***paramount concern***" entitled to deference, which may be diminished if a plaintiff selects a foreign forum (as Genentech did here). (Mar. 5 Op. at 8 (emphasis added) (quoting *Wm. H. McGee & Co., Inc. v. United Arab Shipping Co.*, 6 F. Supp. 2d 283, 289 (D.N.J. 1997))). Indeed, the Court finds no clear error in Judge Wettre's finding that Plaintiffs' choice of forum should not be diminished as much as Defendants would prefer where all parties' strategic decisions likely resulted in the '637 Patent's absence from the Pirfenidone ANDA Litigation in Delaware. (*Id.* at 9–10).

discovery reveal that either lack the necessary proprietary interest in the '637 [P]atent." (emphasis added))). Defendants' footnote makes clear that they did not explicitly argue HLR's purported lack of Article III standing in their moving submission before Judge Wettre.[4] Nor did they raise the issue of Article III standing during the January 12, 2024 Oral Argument. (*See generally* OA Tr.). Moreover, Defendants' footnote reflects that at the time of their motion to transfer, they did not have any evidence to support the notion that either plaintiff lacked Article III standing. (*See* Initial Mov. Br. at 15 n.9; *see also* Mar. 5 Op. at 9 ("Sandoz cites nothing to demonstrate that the licensing of the Patent to Genentech renders HLR an improper party plaintiff, and it provides no further information on the precise terms of the license to support its conjecture that HLR relinquished all rights to the Patent.").

For these reasons, Defendants' failure to argue that HLR lacked standing before Judge Wettre renders the argument waived with respect to Defendants' motion to transfer, both below and on Appeal. *See Laborers' Int'l Union of N.A. v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994) ("[Plaintiff] concedes that [defendant] addressed the arbitration issue in its 1988 reply brief (which was not placed in the record), but argues that by then it was too late to do so. We agree. An issue is waived unless a party raises it in its opening brief . . . ."); *Easterday v. USPack Logistics, LLC*, No. 15-7559, 2020 WL 7137859, at *4 (D.N.J. Dec. 4, 2020) ("Even a passing reference to an issue does not suffice to preserve it."); *Bowen v. Parking Auth. of Camden*, No. 00-5765, 2002 WL 1754493, at *6 (D.N.J. July 30, 2002) ("[A]bsent good cause, the District Judge will not consider new arguments raised on appeal that could have been presented to the

[4] Defendants also failed to argue that HLR lacked standing in their reply brief before Judge Wettre. Instead, Defendants cited to allegations in the Complaint, claimed that "HLR is irrelevant to this litigation," and quoted a Federal Circuit case stating that "transfer[ing] all substantial rights in the patents-in-suit, . . . is tantamount to an assignment of those patents to the exclusive licensee, conferring standing to sue solely on the licensee." (D.E. No. 51 ("Initial Reply Br.") at 13–14 (quoting *Alfred E. Mann Found. For Sci. Rsch. v. Cochlear Corp.*, 604 F.3d 1354, 1358–59 (Fed. Cir. 2010))). The quoted text is the only reference to "standing" in Defendants' initial reply brief.

Magistrate Judge . . . . ").[5]

Furthermore, based on the limited record, Judge Wettre found Defendants "fail[ed] to establish that HLR is not a necessary or proper plaintiff." (Mar. 5 Op. at 9). In so finding, Judge Wettre cited *Lone Star Silicon Innovations LLC v. Nanya Technology Corporation*, which sets forth the nuanced analysis required of any agreement that purports to transfer patent rights. (*Id.* (citing *Lone Star*, 925 F.3d 1225, 1229 (Fed. Cir. 2019) ("In distinguishing between 'an assignment' and a 'mere license,' we 'examine whether the agreement transferred all substantial rights to the patents.'" (internal citations omitted))). Indeed, the "inquiry depends on the substance of what was granted rather than formalities or magic words." *Lone Star*, 925 F.3d at 1129. Thus, Judge Wettre did not err by failing to assess whether all substantial rights were transferred to Genentech because neither the agreement between Genentech and HLR, nor any subset of its terms, were presented for the Court's consideration. Defendants also never presented the agreement or any portions thereof to Judge Wettre for reconsideration before initiating this Appeal.

For all of these reasons, the March 5 Opinion was not clearly erroneous or contrary to law.

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[5] As prefaced above, although Defendants made one vague reference to standing and the Complaint's allegations in their reply brief before Judge Wettre, Defendants waived their Article III standing argument for purposes of this Appeal by failing to include it in their initial moving brief below. (*Compare* Initial Mov. Br. at 15 n.9, *with* Initial Reply Br. at 13–14). Nonetheless, even assuming the issue had been squarely before Judge Wettre, Defendants fail to establish that Genentech's purported holding of an "exclusive license[]" and "all substantial rights to the '637 [P]atent" as alleged in the Complaint (Mov. Br. at 16 (citing Compl. ¶ 16)), were sufficient for Her Honor to hold that HLR lacks Article III standing. Absent from the Complaint are any allegations that HLR ***assigned*** or ***transferred*** all of its substantive rights to Genentech. (*See generally id.*). Thus, based solely on the Complaint's allegations—the only evidence Defendants submit in support of their Article III standing argument as to HLR—their initial argument remains true: "HLR *may have assigned* the ['637] [P]atent[] to Genentech." (Initial Mov. Br. at 27). It logically follows that HLR *may* ***not*** *have assigned* the '637 Patent to Genentech notwithstanding Genentech's alleged holding of an exclusive license with respect to the '637 Patent. *See Alfred E. Mann Found.*, 604 F.3d at 1360 ("When there is an exclusive license agreement, as opposed to a nonexclusive license agreement, but the exclusive license does not transfer enough rights to make the licensee the patent owner, either the licensee or the licensor may sue, but both of them generally must be joined as parties to the litigation."). Indeed, Defendants do not cite any case in which a patent owner such as HLR lacked standing based on allegations in a Complaint alone without examination of a relevant underlying agreement. (*See generally* Mov. Br. & Reply Br.); *see also Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 n.7 (Fed. Cir. 2007) ("[I]n determining whether a party holds the exclusionary rights, we determine the substance of the rights conferred on that party, not to the characterization of those rights as exclusive licenses or otherwise.").

ii. Genentech's Choice of Forum

Next, Defendants argue that the March 5 Opinion should have accorded minimal weight to foreign plaintiff Genentech's choice of forum in New Jersey. (Mov. Br. at 18–19 (claiming that "rather than curb deference to Genentech's choice of forum, the [March 5 Opinion] instead accorded it 'paramount' weight")). In the same vein, Defendants concede the March 5 Opinion "correctly acknowledged that deference to a plaintiff's choice of venue should be diminished when it chooses a 'foreign forum.'" (*Id.* at 18 (citing Mar. 5 Op. at 8)).

As noted above (*supra* n.3), Defendants place improper emphasis on the weight accorded to Plaintiffs' choice of forum as "paramount." The March 5 Opinion merely emphasizes the paramount nature of the first private interest factor. (Mar. 5 Op. at 10). In support of their position that "controlling law requires this factor to be accorded minimal weight," Defendants cite to one case claiming that the court had "discount[ed] plaintiff's forum choice because plaintiff was not at home in the forum." (Mov. Br. at 18 (citing *Teva Pharms. USA, Inc. v. Sandoz Inc.*, No. 17-0275, 2017 WL 2269979, at *5 (D.N.J. May 23, 2017))). *Teva* is inapposite, however, because the court accorded less weight to the foreign plaintiff's choice of forum for an additional reason: the operative facts occurred *outside* of New Jersey. 2017 WL 2269979, at *5 ("[P]laintiff's forum preference is given less deference where, as in this case, the plaintiff has chosen a foreign forum ***and*** the operative facts giving rise to the claim occurred outside of the forum chosen by the plaintiff." (emphasis added)). By contrast, the present matter involves allegations of nationwide generic sales, including within the State of New Jersey. (Compl. ¶¶ 31–32). In addition, as noted by Judge Wettre, defendant Sandoz maintains its principal place of business in New Jersey, making it "likely" that at least some marketing and/or sales decisions regarding generic Esbriet® occurred in this District. (Mar. 5 Op. at 12).

Accordingly, the weight accorded to Genentech's choice of forum in New Jersey—where Sandoz maintains its principal place of business—was not clearly erroneous or contrary to law. *See Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, No. 14-0874, 2015 WL 4036951, at *3 (D. Del. July 1, 2015) ("In light of the fact that Delaware is not Merck's home turf, but is Teva's state of incorporation, the court awards this factor increased weight in the *Jumara* analysis but less than the substantial or paramount weight it would be given had Merck filed suit in its home forum. This factor weighs against transfer." (internal quotation marks and citation omitted)), *report and recommendation adopted*, 2015 WL 4477699 (D. Del. July 22, 2015). And, as noted above (*see supra* n.3), the Court agrees with Judge Wettre in that Plaintiffs' choice of forum should not be diminished as much as Defendants desire where all parties' strategic decisions likely resulted in the '637 Patent's absence from the Pirfenidone ANDA Litigation.

2. Practical Considerations

On balance, Judge Wettre found that the private interest factors did not tip in favor of transfer. (Mar. 5 Op. at 13). Thus, the decision to transfer hinged on whether one or more of the three public interest factors at issue strongly favored transfer. (*Id.*). After holding oral argument and conducting a careful analysis, Judge Wettre found none of the public interest factors balanced in favor of transfer to the District of Delaware. (*Id.*).

With respect to practical considerations—the only public interest factor at issue on Appeal—Judge Wettre noted the absence of pending litigation in the District of Delaware turned her focus on whether Judge Andrews's knowledge of the Pirfenidone ANDA Litigation would "render[] litigation of this case in Delaware more expeditious, more efficient, and less expensive." (*Id.* at 13–14). Judge Wettre ultimately concluded that while Judge Andrews's general knowledge would give him "a head-start that would result in some judicial economy," she noted several

"important differences between this case and the [Pirfenidone ANDA Litigation] that would render that lead insubstantial." (*Id.* at 14–15).

First, Judge Wettre found that the '637 Patent—a formulation patent—is "completely unrelated to the [six] patents tried by Judge Andrews," i.e., method-of-treatment patents. (*Id.* at 15). Specifically, the '637 Patent "claims the use of glidants that 'improve[] the flow properties of the granulate formulation during the manufacturing process and allows for the preparation of more patient friendly pirfenidone tablets." (*Id.* (quoting D.E. No. 49 at 4)). Of the six patents tried by Judge Andrews, four consisted of "Liver Function Test" ("LFT") patents, while two consisted of "Drug-Drug Interaction" ("DDI") patents. (*Id.* at 3 (citing *Genentech, Inc.*, 592 F. Supp. 3d at 360)). The four LFT patents cover methods "for administering pirfenidone to a patient that has exhibited abnormal biomarkers of liver function in response to pirfenidone administration." (*Id.* at 15 (quoting *Genentech, Inc.*, 55 F.4th at 1371)). Meanwhile, the two DDI patents cover "'methods for avoiding adverse interactions between pirfenidone and fluvoxamine' in a patient." (*Id.* (quoting *Genentech, Inc.*, 55 F.4th at 1374)). In addition, Judge Wettre noted Defendants' admission at oral argument that "none of the patents tried in Delaware are in the same 'family'" as the '637 Patent. (*Id.* (citing OA Tr. at 23:18–24:4 (admitting that the '637 Patent "bears no family relationship with the patents that were asserted in Delaware"))).

Next, Judge Wettre assessed Defendants' assertion that the '637 Patent is similar to a *different* formulation patent initially at issue in Delaware—U.S. Patent No. 8,383,150 (the "'150 Patent"). (*Id.*). Because Judge Andrews never construed the '150 Patent following its dismissal from the Pirfenidone ANDA Litigation as "part of the pretrial claims-narrowing process . . . early in fact discovery," Judge Wettre found that Judge Andrews "would have had no reason to learn about any of the formulation patents initially asserted in the prior case, including the '150 Patent."

(*Id.* at 15–16). Thus, she found that Judge Andrews would "not have begun to ascend the learning curve in understanding the formulation patent at issue in this case." (*Id.* at 16).

Second, and relatedly, although Judge Andrews considered whether the LFT and DDI patents were invalid as obvious, the prior art he considered dealt with methods-of-treatment with pirfenidone, not formulation of pirfenidone. (*Id.* at 16). Thus, Judge Wettre credited Plaintiffs' assertion that this matter will not involve any of the same prior art assessed in the Pirfenidone ANDA Litigation. (*Id.*).

Third, Judge Wettre discredited Defendants' argument that secondary considerations of non-obviousness such as "pirfenidone's arduous road to approval, the long felt need for treatments for IPF, and continued skepticism about pirfenidone's safety and efficacy," would contribute to judicial efficiency in Delaware. (*Id.*). In particular, Judge Wettre found that secondary considerations in this matter will likely be different than those at issue in Delaware because they require "a nexus to the claims in the patent at issue" and, as noted above, the patents at issue here are unrelated to those in the Pirfenidone ANDA Litigation. (*Id.*).

Fourth, Judge Wettre found that the present matter asserts a claim for monetary damages, whereas the Pirfenidone ANDA Litigation before Judge Andrews centered on injunctive relief with only the prospect of damages. (*Id.* at 17). For example, she noted that this matter "will go far beyond the arguments about ***prospective loss*** that Judge Andrews considered in the injunction motion," including "a much broader and deeper examination of harm than the Delaware court was required to assess." (*Id.* (emphasis added)). Accordingly, Judge Wettre concluded that Judge Andrews "will not have much of a leg up on the damages phase of this case by virtue of deciding that injunction motion." (*Id.*). Moreover, Judge Wettre alleviated Defendants' concern that certain of Plaintiffs' arguments before Judge Andrews would undercut their position on damages in the

present case by noting that "any prior, inconsistent representations to the Delaware court are of record and as such can be used here." (*Id.*).

Fifth, Judge Wettre disagreed with Defendants' contention that claim preclusion issues in this matter will invoke Judge Andrews's existing knowledge of the '150 Patent. (*Id.*). Specifically, she recognized that claim preclusion will necessarily involve examination of the scope of the '637 Patent's claims and whether those claims are substantially similar to the dismissed claims of the '150 Patent. (*Id.*). However, Judge Andrews did not gain knowledge of the '150 Patent because it was dismissed with prejudice prior to both claim construction and trial. (*Id.* at 17–18). As a result, Judge Wettre found that "there is no apparent judicial economy in having the Delaware court adjudicate the claim preclusion issue" where "[b]oth courts would need to start from scratch in deciding it." (*Id.* at 18).

Finally, Judge Wettre distinguished the parties' cited cases as inapposite because they all turn on their own "unique facts." (*Id.*). Furthermore, she noted a common thread in patent matters that have been transferred; namely, the existence of "closely related patents that have been or will be tried in the transferee forum." (*Id.*). By contrast, courts have denied motions to transfer in patent matters when they involve a comparison of "patents that are distinct." (*Id.* (first citing *Indivior Inc. v. Dr. Reddy's Lab'ys S.A.*, No. 17-7106, 2018 WL 4089031, at *4 (D.N.J. Aug. 27, 2018); and then citing *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharms. LP*, No. 08-4786, 2009 WL 2616816, at *6–7 (E.D. Pa. Aug. 24, 2009))); *see also Pfizer, Inc. v. Sandoz Inc.*, No.06-0090, 2006 WL 8459841, at *2 (D. Del. May 19, 2006) (denying motion to transfer, reasoning in-part that litigation in the transferee forum "involve[d] different patents").

On Appeal, Defendants argue the March 5 Opinion was clearly erroneous and contrary to law because it "discounted Judge Andrews' familiarity with the substantial related and overlapping

facts from the Delaware case by erroneously characterizing those related facts as 'general knowledge.'" (Mov. Br. at 10–11).[6] Defendants' arguments consist of two broad categories, including (i) damages considerations allegedly before Judge Andrews that they contend must be resolved in this action, and (ii) secondary considerations of non-obviousness[7] allegedly known by Judge Andrews that they assert are at issue in the present matter. (*Id.* at 11–16).[8] The Court considers each argument in turn.

i. Damages Considerations[9]

Defendants argue the details of the six patents before Judge Andrews, including the "known useful methods of administering pirfenidone," and the patents' "scope, content and corresponding economic value, must be resolved by th[is] Court in accordance with Federal Circuit law." (Mov. Br. at 12). In support of their position, Defendants contend that the scope of all six

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[6] Defendants also broadly assert that the Delaware litigation "is part-and-parcel of this case" and that trial in this matter will involve "***all twenty*** of the patents asserted in Delaware—including all six patents Judge Andrews addressed at trial." (Mov. Br. at 11 (emphasis added)). Defendants provide no support for these blanket assertions, much less how any purported failure to consider all twenty patents below was clearly erroneous or contrary to law.

[7] Defendants title this subsection of their moving brief "obviousness/secondary considerations." (Mov. Br. at 14). However, this section is more appropriately regarded as "secondary considerations of non-obviousness," as discussed in the parties' briefs. (*See* Opp. Br. at 21–23; *see also* Reply Br. at 1).

[8] Defendants also suggest that the March 5 Opinion made assumptions contrary to law regarding prospective case assignment if this matter were transferred to Delaware. (Mov. Br. at 19–20). Relevant here, in a footnote, Judge Wettre surmised that assignment of this matter to Judge Andrews as "related" to the Pirfenidone ANDA Litigation remained "a mere[] possibility" rather than a "*fait accompli*" because the District of Delaware retains discretion in application of its Local Rules on related case assignments. (Mar. 5 Op. at 14 n.5). Moreover, Judge Wettre took judicial notice of Judge Andrews's recent senior status, which she commented would "presumably" give him "greater discretion to determine which cases to accept as part of his docket." (*Id.*). Because Judge Wettre's analysis of the *Jumara* factors did not depend on these passing hypothetical observations, they are neither clearly erroneous nor contrary to law. Moreover, the Court "is satisfied that Judge [Wettre] was not relying on fatally incorrect assumptions" in making these hypothetical observations. *See Stephen L. LaFrance Pharmacy, Inc. v. Unimed Pharms., Inc.*, No. 09-1507, 2009 WL 3230206, at *5 (D.N.J. Sept. 30, 2009).

[9] It appears Defendants failed to argue below that allegedly overlapping facts between the Pirfenidone ANDA Litigation and this action would aid Judge Andrews's determination of the commercial value attributed to the patented invention at issue in this case, which Defendants contend should occur in isolation from the commercial value attributed to *other* patented inventions at issue in the Pirfenidone ANDA Litigation. (*Compare* Initial Mov. Br., *with* Mov. Br. at 11–12 *and* Reply Br. at 6–8; *see* Opp. Br. at 18). Accordingly, to the extent this argument was not before Judge Wettre, it is waived on Appeal. (*See supra* Section III.A.1.i). Nonetheless, to the extent any aspect of this argument overlaps generally with the practical considerations before Judge Wettre and assessed in the March 5 Opinion, the Court addresses Defendants' subpoints herein.

patents litigated in Delaware, including "their contribution to the body of knowledge regarding pirfenidone, and how each invention is embodied within Esbriet® tablets . . . . were addressed by Judge Andrews during claim construction, trial, and during post-trial injunction proceedings." (*Id.* (citing D.E. No. 49-5 (Judge Andrews's October 20, 2022, Opinion on Claim Construction), D.E. No. 49-3 at 3–10 (Judge Andrews's March 22, 2022 Trial Opinion), and D.E. No. 47-2 at 12–19 (Plaintiffs' March 31, 2022 Brief in Support of Emergency Motion for Temporary Restraining Order and Injunction Pending Appeal))).

Although Defendants argue the March 5 Opinion overlooked "these substantial, related, and overlapping facts from the Delaware litigation, rendering it clearly erroneous and contrary to Federal Circuit law," they do not cite to any decisions that have granted transfer under analogous or partially analogous factual circumstances to those in the present matter. (*See id.* at 13). As noted by Judge Wettre and acknowledged by Defendants, this matter involves a formulation patent that is in an entirely different patent family than the method-of-use patents litigated before Judge Andrews. Defendants proffer no decisions to rebut Judge Wettre's finding that motions to transfer are often denied where, as here, "the patents are distinct." (Mar. 5 Op. at 18).[10] Similarly, while

[10] Defendants' citation to *In re HP Inc.*, 826 F. App'x 899 (Fed. Cir. 2020) in their reply brief, is of no moment. (*See* Reply Br. at 4). There, the court found the transferee court "had gained familiarity over one of the patents" asserted in both the transferee court and the present court such that the transferee court had "at least as much, if not more, experience with relevant issues." *In re HP Inc.*, 826 F. App'x at 903 n.2. Here, the March 5 Opinion made clear that the '637 Patent—a formulation patent not asserted in the Pirfenidone ANDA Litigation—necessarily will involve different issues that were not addressed by Judge Andrews during his trial of six ***different*** method-of-treatment patents.

Moreover, in *In re HP Inc.*, the Federal Circuit took issue with the district court's analysis, which focused on the familiarity it gained by adjudicating personal jurisdiction challenges prior to resolving the motion to transfer. 826 F. App'x at 903. The Federal Circuit reasoned that "[t]he problem with this analysis is that motions to transfer venue are to be decided based on the situation which existed when the suit was instituted." *Id.* (internal quotations omitted). Thus, it continued, "[a]t the time this suit was initiated, [the transferee court] had gained familiarity over one of the patents in presiding over [plaintiff's] earlier suit . . . while the district court . . . had no familiarity with any of the issues." *Id.* Unlike *In re HP Inc.*, Judge Wettre did not support the March 5 Opinion with any familiarity gained by this Court since Plaintiffs filed suit in the District of New Jersey. Furthermore, reassignment of this matter occurred approximately four months ago, and adjudication of the instant Appeal marks the Undersigned's first encounter with the present matter.

Defendants generally cite to Judge Andrews's prior decisions and briefing from the Pirfenidone ANDA Litigation, the alleged overlap in "scope, content and corresponding economic value" of the '637 Patent and the six patents before Judge Andrews remains unclear. Thus, Defendants fail to make any meaningful connection between the categories of purportedly related information litigated in Delaware and the '637 Patent at issue here to render the March 5 Opinion clearly erroneous or contrary to law. Moreover, Defendants also fail to acknowledge how Judge Wettre recognized "that Judge Andrews would have acquired general knowledge at the previous trial on certain subjects that ***may*** arise in this case." (Mar. 5 Op. at 14 (emphasis added)); *see also Indivior Inc.*, 2018 WL 4089031, at *4 ("Judge Andrews, by virtue of ably presiding over the previous case, surely gained relevant expertise. Still, he should not be deemed to have superior familiarity with the issues raised in *this*, non-identical case.").

Next, Defendants challenge Judge Wettre's determination that any "prior[] inconsistent representations to the Delaware court are of record and as such can be used here." (Mov. Br. at 13 (quoting Mar. 5 Op. at 17)). They claim that the existence of a prior record "d[id] not obviate" the "require[d] consideration of Judge Andrews' familiarity with related facts" such that the March 5 Opinion's "'record' exception would swallow the Federal Circuit's rule." (*Id.*). Defendants' extrapolation of a "'record' exception" from the March 5 Opinion is without merit. Indeed, as noted above, Judge Wettre fully considered Judge Andrews's general knowledge from the Pirfenidone ANDA Litigation that may be applicable in the present matter. (Mar. 5 Op. at 14). However, after careful examination of the '637 Patent and its potential relatedness to the patents and issues before Judge Andrews, Judge Wettre found that there are "important differences between this case and the prior action that would render [his] lead insubstantial." (*Id.* at 14–15). Even if this Court disagreed with Judge Wettre's determination—which it does not—disagreement

alone is insufficient to render the March 5 Opinion clearly erroneous or contrary to law. *See, e.g.*, *Toth v. Alice Pearl, Inc.*, 158 F.R.D. 47, 50 (D.N.J. 1994) ("Under the clearly erroneous standard of review, the magistrate judge's findings should not be rejected even if a reviewing court could have decided the issue differently.")).[11]

Finally, although Defendants disagree with Judge Wettre's determination that this matter will involve "a much broader and deeper examination of harm that the Delaware Court was required to assess," (Mov. Br. at 14 (quoting Mar. 5 Op. at 17)), they cite to no specific "significant related facts" familiar to Judge Andrews that they claim are "relevant in this case." (*See generally id.*). Nor do they provide any decisions in support of their assertion that this finding was contrary to law. (*See id.*).

Accordingly, for all the reasons set forth above, Defendants have not established that the March 5 Opinion was clearly erroneous or contrary to law. *See, e.g.*, *Indivior Inc.*, 2018 WL 4089031, at *4 (declining to transfer patent litigation to Judge Andrews despite defendants' citation to purportedly "overwhelming' authority that calls for a transfer where the transferee court has considerable prior experience with the same parties, the same technology, the same subject matter of the asserted patents, and the same accused formulations"); *Teva*, 2009 WL 2616816, at *6 (denying motion to transfer where "different patents [were] at issue in the two cases" such that "the claim construction, prior art, and invalidity arguments relevant to each of the cases will differ"); *see also Siemens Fin. Servs., Inc.*, 2010 WL 3119520, at *5 ("In essence, [p]laintiff simply

[11] Similarly, whether Plaintiffs legitimately barred Defendants from accessing the Delaware record based on the Protective Order entered in the Pirfenidone ANDA Litigation (Mov. Br. at 13–14), was not squarely before Judge Wettre. (*See* Initial Moving Br. at 34 n.15 (stating, in a passing footnote, that "Plaintiffs' counsel have denied Defendants' current counsel access to" "all the documents about the patents from the prior litigation")). Moreover, Defendants' passing reference to their alleged denial of access is embedded in their discussion of the private interest factor on the location of books and records in their initial moving brief—a factor Defendants concede is not at issue on Appeal. (*Compare* Initial Mov. Br. at 33–34, *with* Mov. Br. at 9 (conceding that apart from practical considerations and Plaintiffs' choice of forum, none of the other factors "had a meaningful impact on the decision to deny transfer")). Accordingly, the Court will not consider this argument.

urges the Court to decide the motion differently. This is not a sufficient basis to reverse [Magistrate] Judge Cecchi's decision.").

ii. Secondary Considerations of Non-Obviousness

Next, as related to secondary considerations of non-obviousness, Defendants argue that because Plaintiffs allege the '637 Patent "facilitates patient compliance with prescribed dosing regimens . . . . facts regarding patient compliance with pirfenidone products and factors that might impact compliance or non-compliance with prescribed dosing regimens" are at issue in the present matter. (Mov. Br. at 14 (citing Compl. ¶¶ 5–7 & 13)). Furthermore, Defendants claim that trial and post-trial proceedings from the Pirfenidone ANDA Litigation involved "[r]elated and overlapping facts" that were presented to Judge Andrews. (*Id.* at 14–15 (citing D.E. No. 49-3 (Judge Andrews's March 22, 2022 Trial Opinion) at 12–18)).

In a similar vein, Defendants contend that Plaintiffs' allegation regarding the purported need for Esbriet® tablets in 2016 necessarily means facts prior to 2016 will be at issue in the present matter. (*Id.* at 15 (citing Compl. ¶¶ 5–7 & 13)). According to Defendants, those pre-2016 facts include "the known use of pirfenidone as a treatment for IPF, known dosing regimens for pirfenidone, the availability of pirfenidone therapies, . . . and the 'Breakthrough Therapy' designation granted to Esbriet® capsules but not Esbriet® tablets." (*Id.* (emphasis in original)). Defendants maintain Judge Andrews is already familiar with facts regarding the 'long felt need' for pirfenidone products" before 2016 because they were "detailed in Delaware" during trial and post-trial proceedings. (*Id.* (citing D.E. No. 49-3 at 3–10 & 19–20)).

Defendants maintain the March 5 Opinion "looked past these related facts" based on Judge Wettre's view that it remained "unlikely, . . . that evidence of secondary considerations will necessarily be the same here as that presented in Delaware." (*Id.* (quoting Mar. 5 Op. at 16)).

Finally, Defendants assert that Judge Wettre's reasoning was contrary to law because it required evidence to "necessarily be the same" in both matters, which they contend "is a much higher bar than the Federal Circuit's 'related facts' inquiry." (*Id.*).

First, like the arguments recounted above, Defendants never raised issues regarding allegedly overlapping patient compliance facts before Judge Wettre. (*Compare* Initial Mov. Br., *with* Mov. Br. at 14–15). Accordingly, this argument is waived for purposes of Appeal.[12] Second, Defendants' contention that the March 5 Opinion looked past these allegedly overlapping facts as "unlikely . . . to be the same here" omits Judge Wettre's analysis. Indeed, Judge Wettre explained "[t]his is because secondary considerations require a nexus to the claims in the patent at issue, i.e., there must be a legally and factually sufficient connection between the evidence and the patented invention." (Mar. 5 Op. at 16 (internal quotations omitted)). Thus, because the six method-of-treatment patents tried in Delaware are unrelated to the formulation patent at issue here, Judge Wettre found "it unlikely the relevant secondary considerations evidence would be the same as the evidence presented in the prior action." (*Id.*). Defendants have not cited any case in support of its position that this reasoning is contrary to Federal Circuit law. (*See* Mov. Br. at 14–16).[13]

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[12] In any event, Plaintiffs correctly point out that the portion of Judge Andrews's Trial Opinion cited in support of Defendants' contention—i.e., that overlapping facts exist regarding patient compliance or non-compliance with dosing regimens—does not make any mention of patient compliance; rather, the trial opinion discusses dosing modification in connection with different patents. (*See* Opp. Br. at 21 (citing D.E. No. 49-3 at 12–18)).

[13] Although Defendants argue the March 5 Opinion misapplied the Federal Circuit's "related facts" inquiry (Mov. Br. at 14–15; Reply Br. at 3–4), they do not cite a Federal Circuit decision in support of its position on this alleged inquiry. Indeed, Defendants' position appears to hinge on the district court's paraphrasing in *Vanda*, which states "the Federal Circuit has made clear that a court's familiarity with ***related patents and facts*** from prior litigation . . . is a valid factor for purposes of a motion to transfer." 2023 WL 1883357, at *6 (emphasis added). Defendants construe this statement to argue that the Federal Circuit only requires related facts between two matters, as opposed to factual redundancy. (Mov. Br. at 14–15; Reply Br. at 3–4). This reading of *Vanda*, however, is too literal. Indeed, the Federal Circuit cases cited in *Vanda* refer to the same asserted patents across district courts. *See Vanda*, 2023 WL 1883357, at *6 (first citing *In re EMC Corp.*, 501 F. App'x 973, 976 (Fed. Cir. 2013) ("[W]e have held that a district court's experience with a patent in prior litigation and the co-pendency of cases ***involving the same patent*** are permissible considerations in ruling on a motion to transfer venue." (emphasis added)); and then citing *In re HP Inc.*, 826 F. App'x at 903 (transferring based in part on the fact that "[t]he transferee venue has familiarity with the underlying technology ***and patents***" (emphasis added)); and then citing *In re Google LLC*, 22-0140, 2022 WL 1613192, at *4 (Fed. Cir. May 23, 2022) (explaining that "a court may consider its prior familiarity with ***the asserted***

Moreover, while general background facts on pirfenidone and its treatment for IPF may arise in this litigation, Judge Wettre considered "that Judge Andrews would have acquired general knowledge at the previous trial on certain subjects that ***may*** arise in this case." (*See* Mar. 5 Op. at 14).

Accordingly, as it pertains to secondary considerations of non-obviousness, the March 5 Opinion is not clearly erroneous or contrary to law. *See, e.g.*, *NETGEAR, Inc. v. Ruckus Wireless, Inc.*, No. 10-0999, 2011 WL 3236043, at *3 (D. Del. July 28, 2011) (denying motion to transfer where the patents at issue in separate pending litigation were "of different patent families from the patents-in-suit" and finding the "fact that the pending California actions involve the same basic wireless router technology as that at issue in this lawsuit . . . not compelling" (collecting cases)).

IV. CONCLUSION

For the foregoing reasons, the Court **AFFIRMS** Magistrate Judge Wettre's March 5 Opinion and **DENIES** Defendants' Appeal. An appropriate Order accompanies this Opinion.

Dated: January 3, 2025

s/ *Esther Salas*
Esther Salas, U.S.D.J.

patents in assessing judicial economy considerations for transfer" (emphasis added))); (*see also* Opp. Br. at 14 n.4 (noting that *Vanda*'s cited cases follow the same common thread recognized by Judge Wettre)). Moreover, this Court does not interpret the March 5 Opinion to require precise factual redundancy between this matter and the Pirfenidone ANDA Litigation. Rather, Judge Wettre compared the different method-of-treatment patents before Judge Andrews with the formulation patent here and found that they would involve adjudication of different, unrelated issues and facts.